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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,501	11/02/2001	N. Garison Ruggles	11377-019001	3374

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/053,501	Applicant(s) RUGGLES, N. GARISON	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-23-03 (RCE Request).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 7 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 7 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-23-03; 2-19-04</u> . | 6) <input type="checkbox"/> Other: _____ |

Informalities

Claim 3, second line, the indefinite article "an" is grammatically inconsistent with the pluralized noun "components". Correction is requested.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 1, 3, 6, 7 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/44901 in view of Barabolak et al (USP 6,436,369).

The primary reference discloses aqueous oral care compositions (see page 7, lines 3-9, for example) containing *Glycyrrhiza glabra* extract, a.k.a. "licorice root extract". The prior art extracts are obtained by ethanol extraction and hence are water insoluble; see page 5, line 5, and example 5 at pages 19 and 20, where a water-insoluble powder is recovered. The extracts contain glycyrrhizic and glycyrrhetenic acid (see page 5, lines 3

and 4) and are active against various bacteria which cause plaque and breath malodor; see the first paragraph on page 4.

The primary reference differs from the instant claims insofar as it does not specifically disclose a cationic surfactant. The reference does, however, clearly suggest that the extracts may "be combined with components typically found in oral hygiene products", including "surfactants" generally (page 4, line 15).

Cetylpyridinium chloride, Applicant's preferred species, is a surfactant "typically found in oral hygiene products". See the secondary reference (col. 1, lines 62 and 63, for example), which differs from the instant claims insofar as it does not specifically disclose *G. glabra* extracts. When cetylpyridinium chloride is combined with an emulsifier, the activity of anti-plaque agents is increased due to improved transport by saliva: see the passage spanning col. 2, line 65 to col. 3, line 11.

Accordingly, it would have been obvious to have used cetylpyridinium chloride as the generically suggested "surfactant" of the primary reference oral hygiene compositions, in combination with an emulsifier, motivated by the desire to improve anti-plaque activity as taught by the secondary reference.

2) Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/44901 in view of Barabolak et al, the combination being taken further in view of Norris (USP 2,946,725).

The primary and secondary references and the motivation for their combination are discussed in subsection "1)" supra. The combined disclosures of these references

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differ from instant claim 2 insofar as they do not specify compositions having a pH of less than 5. It is well-known, however, to adjust the pH of oral care compositions to the acidic range (as low as pH 3.5), in order remove the natural film on teeth which interferes with the therapeutic action of such compositions. See the tertiary reference at col. 1, lines 44-61 and col. 2, line 66. (The tertiary reference differs from the instant claims since, *inter alia*, it does not disclose *G. glabra* extracts).

It would have been obvious to have adjusted the pH of the compositions suggested by the combined teachings of the primary and secondary references to an acidic value as low as 3.5, motivated by the desire to facilitate anti-plaque activity as taught by the tertiary reference.

3) Claims 1 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/44901 in view of Barabolak et al, the combination being taken further in view of D'Amelia et al (USP 6,280,769).

The primary and secondary references and the motivation for their combination are discussed in subsection "1)" supra. The combined disclosures of these references differ from instant claims 37-40 insofar as they do not specify an oligosachharide (such as inulin), a divalent metal cation (such as zinc or copper), or mixtures thereof.

The tertiary reference teaches that the combination of inulin, a polyol, and divalent zinc or copper is synergistically effective against bad breath: see col. 4, lines 5-13. (The tertiary reference differs from the instant claims since, *inter alia*, it does not disclose *G. glabra* extracts).

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It would have been obvious to have added a mixture of oligosaccharide, a polyol, and divalent zinc or copper to the oral care compositions suggested by the combined teachings of the primary and secondary references, motivated by the desire to further improve oral hygiene by reducing bad breath as taught by the tertiary reference. (Stated alternatively, bad breath is inevitably associated with plaque and periodontitis, the conditions targeted by the treatments of the primary reference, so it would have been obvious to have used an antiodor agent in combination therewith. Selection of the particular combination of oligosaccharide, a polyol, and divalent zinc or copper would have been motivated by their art-recognized synergistic effectiveness, i.e. the superior activity of that particular combination for that particular purpose).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;
Tuesday: 10-6:30PM;
Wednesday: off;
Thursday: 10-6:30PM; and
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Marianne, can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

